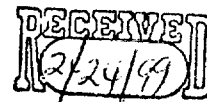




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February 20, 1999



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) The main purpose of these aqueous tissue extracts is to support the patients' hormone-dependent tissue functions until the tissue is able to do so itself.*
- (2) Calcium is also essential for various other body functions, including blood coagulation, muscle contraction, nerve conduction, maintenance and function of cell membranes and membrane permeability, and the proper functioning of many enzymes. The magnesium in this product aids in the uptake of calcium lactate by the body.*
- (2) Calcium and magnesium play a role in phagocytosis in which various types of white blood cells engulf and devour microscopic invaders. Studies show that calcium is necessary for proper functioning of various white blood cells.*
- (3) Calcium supplementation helps maintain a healthy environment in the stomach.*

These statements are made for a dietary supplement containing bovine thymus Cytosol™ extract, calcium lactate, magnesium citrate, cellulose, ascorbic acid, and calcium stearate. The name of the product is Thymex®.

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The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

